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Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket 03P-0453/ Amendment to ANDA Suitability Petition
Request for Waiver of Pediatric Studies

Dear Sir or Madam:

This amendment to Citizen Petition, Docket 03P-0453, submitted September 25, 2003, requests the Secretary to grant a full waiver of the requirement to submit pediatric assessments for a drug under Section 2 of the Pediatric Research Equity Act of 2003 ("PREA"), 21 U.S.C. § 355b(a)(4).

The PREA provides for a waiver if the proposed drug product:

1. Does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and
2. Is not likely to be used in a substantial number of pediatric patients.

The combination ketoprofen-hydrocodone bitartrate tablet for oral administration proposed in Citizen Petition 03P-0453 will not offer a meaningful therapeutic benefit over existing treatments approved for the short-term management of acute pain for pediatric patients, including: hydrocodone bitartrate and acetaminophen elixir for relief of moderate to moderately severe pain in children down to two years of age, acetaminophen with codeine oral solution for the relief of mild to moderate pain in children down to 3 years of age, and Demerol syrup for the relief of moderate to severe pain in pediatric patients. It should not be expected that substitution of an equipotent dose of ketoprofen for acetaminophen in the reference listed drug will offer any meaningful therapeutic benefit over these approved pediatric treatments. A contrary conclusion is warranted. The cited existing treatments are liquid dosage forms more appropriate for use in pediatric patients than the tablet for oral administration proposed in the Citizen Petition.

One should not reasonably expect the proposed ketoprofen-hydrocodone bitartrate tablet to be used in a substantial number of pediatric patients. The reference listed drug product, Vicoprofen®, is a combination opioid and non-steriodal anti-inflammatory drug ("NSAID") used

03P-0453 AMD 1

for the short-term (generally less than 10 days) management of acute pain. Vicoprofen® tablets contain 7.5 mg of hydrocodone bitartrate in combination with a dose of acetaminophen that is an equipotent dose of the NSAID component in the proposed product, ketoprofen. The labeling for Vicoprofen® states that the product is not indicated for the treatment of patients below the age of 16. The proposed product will contain the same precaution. It is not anticipated that the substitution of an equipotent dose of ketoprofen for acetaminophen will change the use of the product, or make it any more likely to be used in pediatric patients.

In conclusion, for the reasons stated above and consistent with Section 2 of the PREA, we respectfully request a full waiver of the pediatric study requirement. Please do not hesitate to contact me at 202-626-2389 if you have any questions regarding this request.

Very truly yours,

Elizabeth S. Crockett

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